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Medical Countermeasures Initiative Update

March 13, 2019



FDA funding opportunity

FDA is seeking research & development to support regulatory science & innovation, including tools to:

- ✓ Support medical countermeasure (MCM) **development and evaluation**
- ✓ Improve, ensure, and secure the **MCM supply chain**



www.fda.gov/medicalcountermeasures

Submit white papers by March 29, 2019

Extramural MCM regulatory science is primarily funded through a [Broad Agency Announcement](#) (BAA) for research and development to support regulatory science and innovation, under area 7: Facilitate Development of Medical Countermeasures to Protect Against Threats to U.S. and Global Health and Security.

The current BAA announcement will remain open until further notice, but proposers are encouraged to submit white papers by **March 29, 2019** for current fiscal year (FY19) awards.

MCM-related research areas of interest include:

- 7.1 - Develop, characterize, and qualify tools to support MCM development under the [Animal Rule](#) or accelerated approval provisions
- 7.2 - Modernize tools to evaluate MCM product safety, efficacy, and quality; and improve, ensure, and secure the MCM supply chain

For more detail on these areas, please view the [full BAA PDF](#) (339 KB). MCM research areas of interest descriptions begin on page 19.

Image at top left: U.S. Public Health Service officers celebrate as a Liberian man adds his handprint to a "survivors' wall." Each patient who overcame Ebola after treatment at the USPHS mobile hospital outside

Monrovia was given a set of clothes and essentials and invited to mark their recovery with a handprint. FDA is funding several research projects to help facilitate Ebola MCM development. (Photo: FDA)

Related information:

- [Learn more and view current MCMi BAA projects](#)
- [Extramural research funded through the BAA](#) (including other research areas)



FDA's Critical Role in Ensuring Supply of Influenza Vaccine

Producing a new vaccine for the next flu season starts well before the current flu season ends. For FDA, it's a year-round initiative. Learn more about our role in this [Consumer Update](#).

Events

- **March 14, 2019:** Webinar - [The Least Burdensome Provisions: Concept and Principles Final Guidance](#), 1:00 - 2:30 p.m. ET. This final guidance describes the guiding principles and recommended approach for FDA staff and industry to facilitate consistent application of least burdensome principles to the activities pertaining to the regulation of medical devices.
- **March 19, 2019:** [Webinar - Implementation of Final Rule on Human Subject Protection: Acceptance of Data from Clinical Investigations for Medical Devices](#), 3:00 - 4:30 p.m. ET
- **March 20-21, 2019:** [Blood Products Advisory Committee meeting](#) (Silver Spring, MD and [webcast](#)) - Matters considered at the meeting will include testing of the blood supply for Zika virus.
- **New! March 26, 2019:** FDA Drug Topics: [An Overview of Pharmacovigilance in the Center for Drug Evaluation and Research \(CDER\)](#) - CE webinar, 1:00 - 2:00 p.m. ET - [Register](#) in advance.
- **March 26-29, 2019:** [Preparedness Summit](#) (St. Louis, MO) - Hosted by NACCHO, this year's theme is "Preparedness Summit 2019: The Evolving Threat Environment." (*fee*)
- **New! April 3-5, 2019:** [Eleventh Annual Sentinel Initiative Public Workshop](#) (Bethesda, MD) - Experts will share recent developments within the Sentinel Initiative, provide training on Sentinel System's tools and data infrastructure, and promote engagement and collaboration with patients, industry and

consumers. Also see the [Sentinel System Five-Year Strategy: 2019-2023](#) (PDF, 1.7 MB)

- **New! April 8, 2019:** Public workshop: [Development of Antibacterial Drugs for the Treatment of Nontuberculous Mycobacterial Infection](#) (Silver Spring, MD and [webcast](#)) - to discuss the clinical trial design considerations, including endpoints, related to the development of antibacterial drug products for treatment of nontuberculous mycobacterial (NTM) disease. Register by **April 4, 2019**.
- **New! April 18, 2019:** [NIIMBL Global Health Fund Workshop: Replacing Animal-based Release Testing for Vaccines](#) (Washington, DC area) - Hosted by the National Institute for Innovation in Manufacturing Biopharmaceuticals, this workshop will explore the current state of animal-based release testing and discuss alternative approaches. Organizers encourage those with in-depth knowledge of *in vitro* vaccine potency and toxicity tests to consider attending.

Information for industry

- [Important Information for Human Cell, Tissue, and Cellular and Tissue-Based Product \(HCT/P\) Establishments Regarding Zika Virus Transmission Risk in the World](#) - The Centers for Disease Control and Prevention (CDC) has changed information on its [Blood and Tissue Safety webpage](#) used to communicate epidemiological information about Zika virus (ZIKV) to the blood and tissue collection community. The webpage includes a [world map of areas with risk of Zika](#) for other countries and territories outside of U.S. states. A new process has been developed to indicate risk for these areas that assigns one of four categories. FDA considers countries and territories outside the U.S. states categorized as “Red” (current outbreak) or “Purple” (any prior or current reports of mosquito-borne Zika transmission) as areas with increased risk of ZIKV transmission. (February 28, 2019) Also see: [Guidance for Industry: Donor Screening Recommendations to Reduce the Risk of Transmission of Zika Virus by Human Cells, Tissues, and Cellular and Tissue-Based Products](#) (PDF, 86 KB, updated May 2018)
- Draft guidance: [Nonproprietary Naming of Biological Products: Update](#) (PDF, 322 KB) - Describes FDA’s current thinking that the nonproprietary names of biological products licensed under section 351 of the Public Health Service Act without an FDA-designated suffix do not need to be revised to add a suffix to accomplish the objectives of the naming convention described in the final guidance for industry on Nonproprietary Naming of Biological Products (Naming Guidance), issued in January 2017. [Comment](#) by **May 7, 2019**. Also see: [Statement from FDA Commissioner Scott Gottlieb, M.D., on FDA’s steps on naming of biological medicines to balance competition and safety for patients receiving these products](#) (March 7, 2019)
- **Reminder:** February 21, 2019 is the effective date for compliance with the [final rule on Human Subject Protection: Acceptance of Data from Clinical Investigations for Medical Devices](#) (Federal Register notice, February 21, 2018). The rule updates the standards for accepting clinical data from clinical investigations conducted inside and outside the United States to protect human participants, and to help ensure the quality and integrity of data obtained through such investigations. On **March 19, 2019**, FDA will host a [webinar for stakeholders](#) who want to learn more about the implementation of this final rule. Also see: [Acceptance of Data from Clinical Investigations for Medical Devices](#)
- In late February, FDA launched two new web pages to support access to *in vitro* diagnostic (IVD) devices during emergencies: [Information for Laboratories Implementing IVD Tests Under EUA](#), and [How to Submit a Pre-EUA for IVDs to FDA](#) (for manufacturers).

More: [MCM-Related Guidance by Date](#)

In case you missed it

[FDA takes new steps to protect food products from deliberate attacks](#) - FDA released a revised draft guidance, [Mitigation Strategies to Protect Food Against Intentional Adulteration](#), to support compliance with the intentional adulteration rule set forth under the FDA Food Safety Modernization Act (FSMA). Also see: [Protecting the Food Supply from Intentional Adulteration, such as Acts of Terrorism](#) (March 5, 2019)

- “Request to Connect” - This [new patient portal](#) gives patients and caregivers a single entry point to the Agency for questions and meeting requests. (March 8, 2019)
- From NIH - [NIH Seeking Input on Tickborne Disease Research Priorities](#) - In response to a recommendation by the HHS Tick-borne Disease Working Group, NIAID is forming a new strategic plan to combat tickborne diseases like Lyme disease, Rocky Mountain spotted fever, babesiosis, and Powassan virus. NIAID will be [accepting comments and suggestions](#) on the plan from stakeholders in scientific research, advocacy, and clinical practice communities, and from the general public until **today, March 13, 2019**.
- From HHS - [HHS' BARDA Funds Its First Marburg Virus Vaccine Development](#) - Vaccine could address an important biodefense and public health threat.
- You want to make a difference. FDA wants to hire you. Follow [@FDAJobs](#) on Twitter, or visit [www.fda.gov/jobs](#).



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